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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,736	07/13/2000	David Frederick Horrobin	P65773US0	4938

7590

10/01/2002

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EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 10/01/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/615,736

Applicant(s)

HORROBIN ET AL.

Examiner

Elli Peselev

Art Unit

1623

-- The MAILING DATE of this communication appears n the cover sheet with the corresp ndence address --

**P r i d for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "fish oil" is not described or suggested by the specification, as originally filed.

Claims 40-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 40-41 are directed to methods for treating or preventing any cardiovascular disorder or cerebrovascular disorder, any form of diabetes or pre-diabetes, any form of psychiatric disorder, any form of neurological or neurodegenerative disorder, any form of kidney disorder, any form of inflammatory or immunological disorder, any form of eye or hearing disorder, any form of obesity and any form of cancer. However, the specification fails to present any evidence that the claimed methods are useful in the treatment and prevention of all the disorders listed in claims 40-41. Since there is no known methods that are useful in the treatment and prevention of all the diseases encompassed by claims 40-41, there is a good reason to doubt that the claimed methods are useful in the treatment and prevention of said diseases.

Claims 17, 20-22, 28-34, 37 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in claim 16 for the terminology "further comprises" Claim 17), "further comprising" (claim 20) and "comprises" (claims 21-22 and 28-34).

There is no antecedent basis in claim 16 for the terminology "or the related compound" (claim 37). Further, it is not clear what specific compounds are encompassed by said terminology.

There is no antecedent basis in claim 16 for the antioxidant in claim 39.

Claims 16-43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the European Patent No. 0,305,907<sup>097</sup>, the European Patent No. 0,198,804 or WO 99/03482.

The European Patent'097 discloses a formulation comprising one or more of the essential fatty acids and vitamins B6, B12, C and E (see, for example, page 12, claims 6 and 10).

The European Patent'804 discloses a formulation comprising essential fatty acids and vitamins B6 and E (see, for example, page 4).

The WO Patent discloses a formulation comprising essential fatty acids, folic acid and vitamins B6, B12 and E.

The claimed compositions are anticipated by the said European Patents and the WO Patent.

In addition, if there are any differences between the claimed compositions and the prior art compositions, the differences would appear to be minor in nature and the claimed compositions, which fall within the scope of the prior art's disclosure, would have been prima facie obvious to a person having ordinary skill in the art at the time the

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instant invention was made. It has been noted that claim 16 has been limited to the terminology "consisting essentially of". Said terminology limits the formulation of claim 16 to the compounds listed and to those compounds which would not materially affect the properties of the claimed formulation. Therefore, claim 16 encompasses additional compounds encompassed by the art of record which would not materially affect the properties of the claimed formulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is 703-308-4616. The examiner can normally be reached on weekdays 8.30 a.m. - 5.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Elli Peselev  
September 27, 2002

*Elli Peselev*  
**ELLI PESELEV**  
**PRIMARY EXAMINER**  
**GROUP 1800**